Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LIXIAO WANG and DONALD J. FOURNIER

Appeal No. 2000-0793
Application No. 08/685,338

ON BRIEF

Before COHEN, FRANKFORT, and OWENS, Administrative Patent Judges.
COHEN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 11 through 17 and 35 through 47. These claims constitute all of the claims remaining in the application. On page 5 of a supplemental reply brief (Paper No. 28), appellants propose to cancel claims 35, 36, and 40 through 42 without presenting any argument relative thereto on appeal. Appellants' statement is taken as an express withdrawal of the appeal as to these claims. Thus, we have before us for appellate review claims 11 through 17, 37 through 39, and 43 through 47.

Appellants' invention pertains to a balloon for a medical device. A basic understanding of the invention can be derived from a reading of exemplary claims 11, 37, 38, and 46, respective copies of which appear in section 9 of the main brief (Paper No. 22).

As evidence of anticipation and obviousness, the examiner has applied the documents listed below:

Cohen et al. (Cohen)	5,167,239	Dec. 1, 1992
Kaneko et al. (Kaneko)	5,344,400	Sep. 6, 1994
Anderson et al. (Anderson)	5,500,180	Mar. 19, 1996 (filed Sep. 30, 1992)

The following rejections are before us for review.

Claim 11 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Anderson.

Claims 12 through 17, 37 through 39, 44 and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Anderson.

Claim 43 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Anderson in view of Kaneko.

Claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Anderson in view of Cohen.

The full text of the examiner's rejections and response to the argument presented by appellants appears in the main and supplemental answers (Paper Nos. 23 and 27), while the complete statement of appellants' argument can be found in the main, reply, and supplemental reply briefs (Paper Nos. 22, 24, and 28). The supplemental answer was in response to a "REMAND TO THE EXAMINER" (Paper No. 26), which remand provided for the filing of the now entered and considered supplemental reply brief (Paper No. 30).

In the main brief (page 8), appellants indicate that as to the anticipation rejection, claim 11 stands or falls alone. As to the first obviousness rejection, claims 12 through 14 stand or fall together, claim 15 stands or falls alone, claims 16 and 17 stand or fall together, claim 37 stands or falls alone, and

claims 38, 39, and 45 stand or fall together. Based upon appellants' comments in the supplemental reply brief (page 7), claim 44 is now grouped with claim 45. As to the obviousness rejection of claim 43, the claim stands or falls alone, while with regard to the obviousness rejection of claims 46 and 47, these claims stand or fall together.

OPINION

In reaching our conclusion on the issues raised in this appeal, this panel of the board has carefully considered appellants' specification[1] and claims, the applied teachings,[2]

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[1] Appellants' "Background of the Invention" section (pages 1 through 4) informs us that, at the time of the present invention, balloons mounted on the distal ends of catheters were widely used in medical treatment. It is particularly worthy of noting that "[t]he requirements for strength and size of the balloons vary widely depending on the balloon's intended use and the vessel size into which the catheter is inserted." We are also instructed that the most demanding applications for balloons are balloon angioplasty, requiring extremely thin walled, high strength, relatively inelastic balloons, while outside that field relatively high compliant, high strength materials are desirable for balloons used on esophageal, pyloric, colonic and anastomotic catheters. On page 12 of the specification, we are informed of a known balloon shrinking process for noncompliant material balloons disclosed in U.S. Patent No. 5,348,538.

[2] In our evaluation of the applied prior art, we have considered all of the disclosure of each document for what it (continued...)

and the respective viewpoints of appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The anticipation rejection

We sustain the rejection of claim 11 under 35 U.S.C. § 102(e) as being anticipated by Anderson.

In the referenced "REMAND TO THE EXAMINER," it was expressly recognized that claim 11 "is a product-by-process claim" (page 2), and that "a prima facie case of unpatentability of a product-by-process claim is made out when the prior art discloses a product which reasonably appears to be either identical with (§ 102) or only slightly different than (§ 103)

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[2](...continued)
would have fairly taught one of ordinary skill in the art. See In re Boe, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1966). Additionally, this panel of the board has taken into account not only the specific teachings, but also the inferences which one skilled in the art would reasonably have been expected to draw from the disclosure. See In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

the claimed product. In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)" (page 3). It follows, as pointed out in In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985), that in a product-by-process claim the claimed product can be unpatentable even though it is made by a different process.

Claim 11 reads as follows.

> A balloon for a medical device made by the method of: forming a balloon for a medical device, wherein a tubing of a thermoplastic polymer material is radially expanded under a first elevated pressure at an elevated temperature to form the balloon at a first diameter, the thermoplastic polymer material being a block copolymer material and the method including the further step of annealing the balloon at a second elevated temperature less than the first elevated temperature and a second pressure less than the first elevated pressure for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter.

Claim 11 reveals to us that the claimed balloon is characterized by what we perceive as fairly broad method recitations addressing the balloon fabrication parameters of temperature, pressure, and (degree of) shrinking. To anticipate the balloon (product) of claim 11 (defined by the characteristics imparted to it by the broad method recitations), the prior art

Anderson patent must disclose a balloon which reasonably appears to be identical to the claimed balloon. As more fully explained below, we conclude that the Anderson patent establishes a prima facie case of anticipation.

Considering the teaching of Anderson, as a whole, we readily appreciate similar conditions to which the patentee's block copolymer balloon is subjected in the making thereof, vis-à-vis appellants' process, to establish in our minds a sound basis for supporting the view that one skilled in the medical balloon art would reasonably expect Anderson's balloon to be identical to the claimed balloon. As expressly stated by patentee Anderson (column 11, lines 2 through 5), "[t]he sterilization process appears to be an important factor in determining the final physical characteristics of the balloons and balloon catheters of this invention." Thus, this panel of the Board takes into full account in the fabrication process of the Anderson balloon the heat set step (Example 1) and the sterilization step (Examples 2 and 3) assessing the similarity therewith to the process steps and conditions evident in appellants' claim 11. As we see it, one practicing the medical

balloon art would have recognized the temperature and pressure changes during the Anderson fabrication process to be akin to those established by the broad recitations of claim 11 such that it would be reasonably expected that the relatively lower sterilization temperature would shrink the block copolymer balloon and establish a diameter to some extent or degree less than the diameter that results as a consequence of the heat set step.[3] Based upon the above analysis, we believe it both fair and reasonable to conclude that those skilled in the medical balloon art would have good and sufficient reasons to expect that the block copolymer balloon made according to the Anderson procedure would be identical to the block copolymer balloon defined by appellants' product-by-process claim 11.

The lack of anticipation arguments in the main (pages 8 through 12), reply (pages 1 through 5), and supplemental reply (pages 1 through 5) briefs advanced by appellants fail to persuade us that those practicing the art at issue would not

[3] It further appears to us that pressurized balloon cooling at 37°C (Example 1) would be reasonably expected to effect a degree of block copolymer shrinking.

have a reasonable basis for making the determination that the compliant block copolymer balloon product of the Anderson process reasonably appears to be identical to the claimed balloon product. In other words, on the basis of appellants' assertions alone, viewed in conjunction with the specified procedure conditions of Anderson, we do not discern relative to the claimed and reference balloons that the "final products are physically distinct" (main brief, page 8). We have, of course, fairly considered all process steps in appellants' claim 11 in assessing features imparted to the claimed medical balloon, in particular the balloon diameter shrink recitation (reply brief, page 3). However, akin to the examiner's assessment (supplemental answer, pages 5 and 6) we have also considered the complete process of the Anderson disclosure (heat set step and sterilization step described by the patentee in Examples 1 through 3) in making our anticipation determination. In the supplemental reply brief (page 4), appellants indicate that although the sterilization process or step is "an important part" of the Anderson disclosure, "it is not meant to alter the physical characteristics of the balloon, let alone shrink the balloon as required by claim 11." Contrary to appellants' point of view, and as pointed out,

supra, patentee Anderson expressly states (column 11, lines 3 through 5) that the sterilization process is an "important factor in determining the final physical characteristics of the balloons and balloon catheters of this invention." As we have explained earlier, and unlike appellants perception (supplemental reply brief, page 4), the effect of sterilization finally determining the physical characteristics of the Anderson balloons is reasonably assessed as effecting a degree of shrinking, leading to a lesser second diameter; all that claim 11 requires in that respect. In light of our analysis of the balloon fabrication process of Anderson, the argument (supplemental reply brief, pages 4 and 5) that the resulting balloons of Anderson "do not appear to be identical" is simply not convincing.

The obviousness rejections

We sustain the rejection of claims 12 through 17, 37 through 39, 44 and 45 under 35 U.S.C. § 103(a) as being unpatentable over Anderson.

Basically, the examiner's rationale in rejecting appellants' claims, founded upon the compliant medical balloon

teaching of Anderson (supplemental answer, pages 6 and 7), is that the selection of parameter values, as set forth in each of the claims at issue, would have been well within the level of skill of the ordinary artisan and achieved through routine experimentation in determining optimal results. We are in general agreement with the examiner's assessment.

It is well established that the discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980).

We have fully considered each of the argued claims under rejection and ascertained that they individually define a balloon for a medical device in terms of identified variable or parameter values, as follows.

Dependent claim 12 addresses a particular bursting pressure parameter, a specified diameter range, and a specific diameter growth (claims 12 through 14 stand or fall together).

Dependent claim 15 sets forth a specific bursting pressure parameter, a specified diameter range, and a specific diameter growth.

Dependent claim 16 recites a specific bursting pressure parameter, a specified diameter range, and a specific diameter growth (claims 16 and 17 stand or fall together).

Independent claim 37 sets forth a balloon for a medical device characterized by a specific bursting pressure parameter, a specified diameter range, and a specific diameter growth.

Independent claim 38 addresses a balloon for a medical device characterized by a specific bursting pressure parameter, a specified diameter range, and a specific diameter growth (claims 38, 39, and 45 stand or fall together).

The Anderson document, in particular, makes it quite evident to us that those having ordinary skill in the compliant medical balloon art at issue, at the time of appellants' invention, were very well versed as to the working parameters or

variables pertaining thereto, i.e., the parameters or variables in the claims at issue. As such, we are certain that those having ordinary skill would have had the requisite knowledge and ability to fabricate a medical balloon according to the teachings of Anderson, determining optimal parameter values for known relevant variables through ordinary experimentation, to thereby produce balloons suitable for the requirements of selected known surgical procedures employing balloons. For the preceding reasons, the rejection of the specified claims under 35 U.S.C. § 103(a) is clearly sound.

Having fully reviewed the arguments of appellants in the main (pages 13 through 20), reply (pages 5 and 6), and supplemental reply (pages 5 through 7) briefs, our opinion is not altered as to the obviousness of the claims under rejection. Appellants point out that claims 12 through 14 target angioplasty balloons, while other specified claims target larger or distinctly different types of balloons which are used for different purposes or applications, and that, in effect, Anderson would not have been suggestive thereof. We are not in accord with appellants' conclusion. From our perspective, one having

ordinary skill in the art would have readily derived from the overall teaching of Anderson an appreciation of the wide applicability thereof to surgical procedures employing balloons that are common and routine, such as the given example of angioplasty procedures (column 1, lines 7 through 13).[4]

We do not sustain the rejection of claim 43 under 35 U.S.C. § 103(a) as being unpatentable over Anderson in view of Kaneko.

Simply stated, a collective assessment of the Anderson and Kaneko teachings indicates to us that one having ordinary skill in the art would not have derived any suggestion therefrom to configure the balloon catheter of Anderson from at least two concentric layers of different thermoplastic polymers. We reach this conclusion since, like appellant (supplementary reply brief, pages 7 and 8), it appears to us that those of ordinary skill in the art would have recognized that the effect of using two

[4] This view is buttressed by the earlier noted statement by appellants on page 1 of the specification as to the knowledge in the art concerning balloon strength and size requirements that are dependent upon intended use and vessel size.

different thermoplastic polymers in fabricating a balloon following the Anderson method (heat set process and sterilization process) would clearly be uncertain. As such, the proposed modification would not have been obvious.

We sustain the rejection claims 46 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Anderson in view of Cohen.

As we see it, those having ordinary skill in the art would have fully understood that the balloon catheter of Anderson was well capable and suitable, when fabricated to an appropriate size, to have utility in the claimed, known gastrointestinal treatment method. Clearly, Anderson contemplates broad medical balloon usage (column 1) encompassing known balloon treatment procedures such as the known gastrointestinal balloon catheter treatments revealed by Cohen (col. 1, lines 41 through 55). For the preceding reasons, the rejection is well founded.

According to appellants' supplemental reply brief (pages 8 and 9), claims 46 and 47 are directed to larger

balloons, and balloons for the gastrointestinal tract were not contemplated by Anderson. Further, appellants view the Cohen patent as addressing a different device for a different purpose, quite different from the angioplasty balloon teaching of Anderson. We are not persuaded by this argument which we understand as being based upon an overly narrow appreciation of the teaching of Anderson. We make reference to our earlier discussion as to the scope and the applicability of the Anderson teaching to other known surgical procedures employing balloons. On that basis, the rejection of claims 46 and 47 is clearly sound.

In summary, this panel of the board has sustained the rejections of all claims on appeal, but for the rejection of claim 43.

The decision of the examiner is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

IRWIN CHARLES COHEN)
Administrative Patent Judge)
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)
Charles E. Frankfort) BOARD OF PATENT
CHARLES E. FRANKFORT) APPEALS
Administrative Patent Judge) AND
) INTERFERENCES
)
)
Terry J. Owens)
TERRY J. OWENS)
Administrative Patent Judge)

Appeal No. 2000-0793
Application No. 08/685,338

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

BOARD OF APPEALS DECISIONS

Serial number: 08/685338

Decision:

Affirmed	Reversed	Affirmed in Part	Remand
		✓	

Decision date: September 30, 2002

Examiner: Rodriguez, Cris

Art Unit: 3763

	Initials	date
QAS :		12/17/02
SPE :		1/27/03
Examiner :		1/6/03

Comments:

Application/Interference Number 08/685338

		DATE	INITIALS
Mail Personnel			
Receive case and PALM to BPAI.			
Docket Personnel I			
OB\Heard Classification			
Outline Case			
Reviewers			
Review/assign panel	(ASSIGN)	5-7-01	PSB
Prepare order/remand	REMAND	6-11-01	PSB
Docket Personnel I	(ASSIGN)	5-6-02	PSB
Enter Data in ACTS/PALM			
Prep case (if panel assigned)			
Docket Personnel I			
Mail remand/order			
Administrators			
Assign Hearing Date			
Docket Personnel II			
Mail Notice of Hearing			
Enter Hearing Data in ACTS/PALM			
Paralegals/Legal Technician			
Type Decision			
Enter Data in ACTS/PALM			
Docket Personnel I			
Send case to_____.			

DESIGNATION OF PANEL

Pursuant to (1) the Commissioner's authority to designate the members of the Board of Patent Appeals and Interferences to hear cases before the Board (35 U.S.C. §7(b)), and (2) Commissioner Lehman's memorandum dated May 12, 1994 (delegating to the Chief Administrative Patent Judge the responsibility of designating members to hear cases before the Board), it is ORDERED that the panel of the Board of Patent Appeals and Interferences designated to decide this case shall consist of the following members of the Board:

X On Brief ___ Heard ___ Redesignation ___ Expanded Panel see addendum

Judge ~~CALVERT~~ FRANKFORT (OB) 4/4-30-02

Judge COHEN

Judge ~~ABRAMS~~ OWENS

OK BTF 9/30/02

BRUCE H. STONER, JR.
Chief Administrative Patent Judge

Date of Oral Hearing:_____